APR 19 2006 W

EXPRESS MAIL NO.: EV 654 849 595 US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of:

Stavenhagen et al.

Confirmation No.:

8663

Application No.:

10/754,922

Art Unit:

1643

Filed:

January 9, 2004

Examiner:

Tungaturthi, Parithosh K.

For:

Identification and Engineering of Antibodies with Variant Fc Regions

...

Attorney Docket No.: 11183-004-999

and Methods of Using Same

<u>INFORMATION DISCLOSURE STATEMENT</u> <u>UNDER 37 C.F.R. § 1.56 AND § 1.97</u>

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

In accordance with the duty of disclosure imposed by 37 C.F.R. § 1.56 and § 1.97 to inform the Patent and Trademark Office of all references coming to the attention of each individual associated with the filing or prosecution of the subject application, which are or may be material to the patentability of any claim of the application, Attorneys for Applicants hereby direct the Examiner's attention to references A01-A33, B01-B27, and C01-C144, which are listed on the attached List of References Cited by Applicant. Pursuant to 37 C.F.R. § 1.98(a)(2)(ii), copies of the cited U.S. patents and published U.S. applications (*i.e.*, references A01-A33) are not submitted herewith. Copies of references B01-B27 and C01-C144 are submitted herewith.

Identification of the listed references is not to be construed an admission of Applicants or Attorneys for Applicants that such references are available as "prior art" against the subject application.

Applicants respectfully request that the Examiner review the foregoing references and that the references be made of record in the file history of the application.

Pursuant to 37 C.F.R. § 1.97(b)(3), since this Information Disclosure Statement is being filed before the mailing of a first Office Action on the merits, it is believed that no fee is due in connection herewith. However, should the Patent Office determine otherwise, please charge the required fee to Jones Day Deposit Account No. 50-3013.

Respectfully submitted,

Date: April 19, 2006

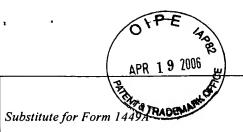
7 40,922 B. Brivanlou (Reg. No.)

Margaret B. Brivanlou
JONES DAY

222 E. 41st Street

New York, New York 10017

(212) 326-3939



LIST OF REFERENCES CITED BY APPLICANT

(Use several sheets if necessary)

ATTY. DOCKET NO. 11183-004-999	APPLICATION NO. 10/754,922
APPLICANT Stavenhagen et al.	
filing date January 9, 2004	art unit 1643

*EXAMINER			_		PAGES, COLUMNS, LINES, WHERE RELEVANT PASSAGES OR RELEVANT
INITIAL	A01	DOCUMENT NUMBER 2003/0158389	08/21/03	Idusogie et al.	FIGURES APPEAR
	A02	2004/0002587	1/1/04	Watkins et al.	
	A03	2004/0110226	6/10/04	Lazar et al.	
	A04	2004/0132101	7/8/04	Lazar et al.	
	A05	2004/0185045	9/23/04	Koenig et al.	
	A06	2005/0054832	3/10/05	Lazar et al.	
	A07	4,752,601	06/21/88	Hahn	
	A08	5,348,876	09/20/94	Michaelson et al.	
	A09	5,576,184	11/19/96	Better et al.	
	A10	5,585,089	12/17/96	Queen et al.	
<u></u>	A11	5,624,821	4/29/97	Winter et al.	
	A12	5,648,260	07/15/97	Winter et al.	
	A13	5,698,449	12/16/97	Baumann et al.	
	A14	5,723,584	3/3/98	Schatz	
	A15	5,736,135	4/7/98	Goeddel et al.	
	A16	5,736,137	04/07/98	Anderson et al.	
	A17	5,874,239	2/23/99	Schatz	
	A18	5,932,433	8/3/99	Schatz	
	A19	5,985,599	11/16/99	Mckenzie et al.	
	A20	6,025,485	2/15/00	Kamb et al.	
	A21	6,114,147	9/5/00	Frenken et al.	
_	A22	6,165,745	12/26/00	Ward et al.	
	A23	6,194,551	2/27/01	Idusogie et al.	
	A24	6,242,195	06/05/01	Idusogie et al.	
	A25	6,277,375	08/21/01	Ward	·
	A26	6,300,065	10/9/01	Kieke et al.	
	A27	6,331,391	12/18/01	Wittrup et al.	
	A28	6,423,538	7/23/02	Wittrup et al.	
	A29	6,455,263	9/24/02	Payan	

EXAMINER	DATE CONSIDERED

Substitute for Form 1449A	ATTY. DOCKET NO. 11183-004-999	APPLICATION NO. 10/754,922	
LIST OF REFERENCES CITED BY APPLICANT	APPLICANT Stavenhagen et al.		
(Use several sheets if necessary)	FILING DATE January 9, 2004	ART UNIT	

U.S. PATENT DOCUMENTS					
	A30	6,528,624	03/04/03	Idusogie et al.	
-	A31	6,538,124	03/25/03	Idusogie et al.	
	A32	6,737,056	5/18/04	Presta	
	A33	6,821,505	11/23/04	Ward	

			rOREIG	N PATENT DOCUMENTS		
		FOREIGN PATENT DOCUMENT COUNTRY CODE, NUMBER, KIND CODE (IF KNOWN)	DATE	NAME	PAGES, COLUMNS, LINES, WHERE RELEVANT PASSAGES OR RELEVANT FIGURES APPEAR	Т
	B01	EP 0 327 378	0809/89	The Trustees of Columbia University		
	B02	WO 88/07089	09/22/88	Medical Research Council		
	B03	WO 89/07142	08/10/89	Morrison, S.		
	B04	WO 92/16562	10/01/92	Lynxvale Limited		
	B05	WO 93/22332	11/11/93	Board of Regents, University of Texas System		
	B06	WO 94/18330	8/18/94	Unilever PLC		
	B07	WO 94/29351	12/22/94	Morgan, S. et al.		
	B08	WO 95/05468	02/23/95	Lynxvale Limited		
	B09	WO 97/28267	08/07/97	Repligen Coroporation		
	B10	WO 97/34631	09/25/97	Board of Regenets, The University of Texas System		
	B11	WO 97/44362	11/27/97	Protein Design Labs, Inc.		
	B12	WO 98/05787	02/12/98	Bristol-Myers Squibb Company		
	B13	WO 98/23289	06/04/98	The General Hospital Corporation		
1	B14	WO 98/52975	11/26/98	Duetches Krebsforschungzentrum Stiftung Des Offentlichen Rechts		
	B15	WO 99/43713	09/02/99	Lexigen Pharmaceuticals Corporation		
1	B16	WO 99/51642	10/14/99	Genentech, Inc		
	B17	WO 99/58572	11/18/99	Cambridge University Technical Services Limited		
	B18	WO 00/09560	02/24/00	Abgenix, Inc.		
	B19	WO 00/42072	7/20/00	Genenech, Inc.		

EXAMINER	DATE CONSIDERED

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Substitute for Form 1449A	ATTY. DOCKET NO. 11183-004-999	APPLICATION NO. 10/754,922	
LIST OF REFERENCES CITED BY APPLICANT	APPLICANT Stavenhagen et al.		
(Use several sheets if necessary)	FILING DATE January 9, 2004	ART UNIT 1643	

			FOREIG	N PATENT DOCUMENTS	
	B20	WO 02/060919	08/0802	Medimmune, Inc.	
	B21	WO 02/086070 .	10/31/02	Dyax Corporation, Inc.	
	B22	WO 03/074679	09/12/03	Xencor	
-	B23	WO 04/029207	04/08/04	Xencor	
	B24	WO 04/074455	09/02/04	Applied Molecular Evolution, Inc.	
	B25	WO 04/099249	11/18/04	Xencor	
	B26	WO 05/070963	08/04/05	Applied Molecular Evolution, Inc.	1000
	B27	WO 06/020114	02/23/06	Applied Molecular Evolution, Inc.	

	OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)
C01	Altman et al., Phenotypic Analysis of Antigen-Specific T Lymphocytes", Science 274:94-96, 1996
C02	Angal et al., Mol Immunol 30 :105-108, 1993
C03	Armour et al., Biochemical Society Transactions 30 :495-500, 2002
C04	Armour et al., Eur J Immunol 29 :2613-2624, 1999
C05	Armour et al., Mol Immunol 40:585-593, 2003
C06	Baggiolini M, Dewald B. Experientia. Oct 15;44(10):841-848, 1988
C07	Boder and Wittrup, 1997, "Yeast surface display for screening combinatorial polypeptide libraries", Nature Biotechnology 15:553-557
C08	Boder and Wittrup, Biotechnol Prog 14:55-62, 1998
C09	Boder and Wittrup, Methods in Enzymology 328:430-444, 2000
C10	Boder et al., Proc. Natl. Acad. Sci. USA 97:10701-10705, 2000
C11	Bredius et al., Immunology 83:624-630, 1994
C12	Brekke et al., Eur J Immunol 24:2542-2547, 1994
C13	Brown EJ., Vol. 45 (Microbes as Tools for Cell Biology) in <i>Methods In Cell Biology</i> , Russell ed. Academic Press Inc. pp.147-64, 1994
C14	Burlmeister et al., Nature 372:379-383, 1994
C15	Burton and Woof, Advances in Immunology 51:1-84, 1992
C16	Burton et al., Mol Immunol 25:1175-1181, 1988
C17	Burton, Mol Immunol 22:161-206, 1985
C18	Canfield and Morrison, J Exp Med 173:1483-1491, 1991
C19	Caron et al., J Exp Med 176:1191-5, 1992
C20	Carter et al., Proc. Natl. Acad. Sci. USA 89:4285-4289, 1992

EXAMINER	DATE CONSIDERED

Substitute for Form 1449A	ATTY. DOCKET NO. 11183-004-999	APPLICATION NO. 10/754,922
LIST OF REFERENCES CITED BY APPLICANT	APPLICANT Stavenhagen et al.	
(Use several sheets if necessary)	FILING DATE January 9, 2004	ART UNIT 1643

		OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)
	C21	Catron et al., Blood 99:754-758, 2002
•	C22	Chappel et al., Proc. Natl. Acad. Sci USA 88:9036-9040, 1991
	C23	Chappel et al., J Biol. Chem 268:25124-25131, 1993
	C24	Ciccimarra et al., PNAS 72 :2081-2083, 1975
	C25	Clynes and Ravetch, Immunity 3:21-26, 1995
	C26	Clynes et al., J Exp Med 189:179-185
	C27	Clynes et al., Nature Medicine 6:443-446, 2000
	C28	Clynes et al., PNAS 95:652-656, 1998
	C29	Clynes et al., Science 279:1052-1054, 1998
	C30	de Haas, Wien Kin Wochenscha 113:825-831, 2001
	C31	Deisenhofer, Biochem. 20:2361-2370, 1981
	C32	Deo et al., Immunology Today 18:127-135, 1997
	C33	Duncan and Winter, Nature 332:738-740, 1988
	C34	Duncan and Winter, Nature 332:563-564, 1988
	C35	Flesch and Neppert, J Clin Lab Anal 14:141-156, 2000
	C36	Gergeley et al., Biochemical Society Transactions 12:739-743, 1984
	C37	Gergely and Sarmay, FASEB J 4:3275-3283, 1990
	C38	Greenwood and Clark, Effector functions of matched sets of recombinant human IgG subclass antibodies. (final version edited Feb. 11, 1993)
	C39	Greenwood et al., Eur J Immunol 23:1098-1104, 1993
	C40	Greenwood et al., Therapeutic Immunology 1:247-255, 1994
	C41	Hadley et al., Immunology 76:446-451, 1992
	C42	Hatta et al., Genes and Immunity 1:53-60, 1999
	C43	Hayes, Fc Engineering to Enhance Monoclonal Antibody Effector Functions. (Presentation) Xecor, CA, 2003
_	C44	Herzenberg et al., Clinical Chem. 2002:48:1819-1827, 2002
	C45	Heyman, Annu Rev Immunol 18:709-737, 2000
	C46	Hogarth et al., Immunomethods 4:17-24, 1994
<u>-</u>	C47	Holler et al., PNAS 97 :5387-92, 2000
	C48	Hulett et al., J. Biol. Chem. 269:15287-15293, 1994
	C49	Hulett et al., J. Biol. Chem. 270:21188-21194, 1995
	C50	Hulett et al., J Immunol 147:1863-1868, 1991

Substitute for Form 1449A	ATTY. DOCKET NO. 11183-004-999	APPLICATION NO. 10/754,922
LIST OF REFERENCES CITED BY APPLICANT	APPLICANT Stavenhagen et al.	
(Use several sheets if necessary)	FILING DATE January 9, 2004	art unit 1643

 C51	Idusogie et al., J Immunol 164: 4178-4184, 2000
 C52	Idusogie et al., J Immunol 166:2571-2575, 2001
 C53	Isaacs et al., Clin Exp Immunol 106:427-433, 1996
 C54	Isaacs et al., J Immunol 148:3062-3071, 1992
 C55	Isaacs et al., J Immunol 161 :3862-3869, 1998
 C56	Jassal et al., Biochem Soc Trans 26:S113, 1998
 C57	Jefferis and Lund, Immunology Letters 82:57-65, 2002
 C58	Jefferis et al., Immunol Lett 44:111-7, 1995
 C59	Jefferis et al., Immunol Rev 163:59-76, 1998
C60	Jefferis et al., Mol Immunol 27 :1237-1240, 1990
C61	Jendeberg et al., J Immunological Methods 201 :25-34, 1997
C62	Kadar et al., Immunol Lett 32:59-63, 1992
C63	Kadar et al., Int J Immunpharmacol 13:1147-55, 1991
C64	Kato et al., J Mol Biol 295:213-224, 2000
C65	Keler et al., J. of Immunol. 164:5746-52, 2000
C66	Kieke et al., PNAS 96 :5651-56, 1999
C67	Kim et al., J Mol Evol 53:1-9, 2001
 C68	Klein et al., PNAS 78 :524-528, 1981
C69	Koene et al., Blood 90 :1109-1114, 1997
C70	Kranz et al., J. Biol. Chem. 257:6987-6995, 1982
C71	Lehmann et al., J Immunol Methods. 243(1-2):229-42, 2000
C72	Lehrnbecher et al., Blood 94:4220-4232, 1999
C73	Li et al., J Exp Med 183:1259-1263, 1996
 C74	Liu et al., J. Immunol. 139:3521-3526, 1987
C75	Lund et al., Eur J Biochem 267 :7246-57, 2000
C76	Lund et al., FASEB J 9:115-119, 1995
C77	Lund et al., J Immunol 147 :2657-62, 1991
C78	Lund et al., J Immunol 157:4963-4969, 1996
C79	Lund et al., Molecular Immunology 29:53-59, 1992
C80	Maenaka et al., J Biol Chem 48 :44898-904, 2001
C81	Michaelsen et al., Immunolgy 91:9243-9247, 1994

EXAMINER	DATE CONSIDERED	

Substitute for Form 1449A	ATTY. DOCKET NO. 11183-004-999	APPLICATION NO. 10/754,922
LIST OF REFERENCES CITED BY APPLICANT	APPLICANT Stavenhagen et al.	
(Use several sheets if necessary)	FILING DATE January 9, 2004	ART UNIT 1643

C82	Morgan et al., Immunology 86:319-324, 1995
C83	Morrison et al., Immunologist 2:119-124, 1994
C84	Munn et al., J Exp Med. 172(1):231-7, 1990
C85	Nagarajan et al., J Biol Chem 270 :25762-25770, 1995
C86	Neuberger et al., Nature 312 :604-608, 1984
C87	Norderhaug et al., Eur J Immunol 21:2379-84, 1991
C88	Nose and Leanderson, Eur J Immunol 19:2179-81, 1989
C89	Okazaki et al., J Mol Biol 336 :1239-1249, 2004
C90	Orfao and Ruiz-Arguelles, Clinical Biochem. 29:5-9, 1996
C91	Partridge et al., Mol Immunol. 23(12):1365-72, 1986
C92	Perussia "Human Natural Killer Cell Protocols" in <i>Methods Molecular Biology</i> . vol. 121 (Campbell et al. eds.) Humana Press Inc., Totowa, NJ. 179-92, 2000
C93	Radaev and Sun, Molecular Immunology 38:1073-1083, 2001
C94	Ravetch and Bolland, Annu Rev Immunol 19:275-90, 2001
C95	Ravetch and Clynes, Annu Rev Immunol 16:421-432, 1998
C96	Ravetch and Kinet, Annu Rev Immunol 9:457-492, 1991
C97	Ravetech and Lanier, Science 290:84-89, 2000
C98	Redpath et al., Hum Immunol 59:720-727, 1998
C99	Reff et al., Blood 83:435-445, 1994
C10	Riechmann et al., Nature. 332(6162):323-7, 1988
C10	Sarmay et al., Eur J Immunol 18:289-294, 1988
C10	Sarmay et al., Mol Immunol 21:43-51, 1984
C10	
C10	Sautes-Fridman et al., ASHI Quarterley, 4 th Quarter: 148-151, 2003
C10	Schaffner et al., Mol Immunol 32 :9-20, 1995 (Erratum in 32 :1299, 1995)
C10	Schatz et al., Bio/Technology 11:1138-1143, 2000
C10	Sensel et al., Molecular Immunology 34:1019-1029, 1997
C10	Shields et al., J Biol Chem 276:6591-6604, 2001
C10	Shopes et al., J Immunol 145 :3842-3848, 1990
C11	Shopes, J Immunol 148 :2918-2922, 1992
C11	Shopes, Molecular Immunology 30 :603-609, 1993

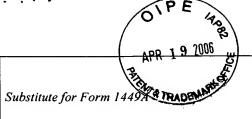
EXAMINER	DATE CONSIDERED

Substitute for Form 1449A	ATTY. DOCKET NO. 11183-004-999	APPLICATION NO. 10/754,922
Substitute your Torm Trivia	APPLICANT	
LIST OF REFERENCES CITED BY APPLICANT	Stavenhagen et al.	
(Use several sheets if necessary)	FILING DATE	ART UNIT
	January 9, 2004	1643

		OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)
	C112	Shusta et al., J Mol Biol 292:949-956, 1999
-	C113	Shusta et al., Nature Biotechnology 16:773-777, 1998
	C114	Shusta et al., Nature Biotechnology 18:754-759, 2000
	C115	Smith and Morrison, Bio/Technology 12:683-688, 1994
_	C116	Sondermann and Oosthuizen, Immunology Letters, 82:51-56, 2002
	C117	Sondermann et al., J. Mol. Biol. 309:737-749, 2001
	C118	Sondermann et al., EMBO J 18:1095-1103, 1999
	C119	Sondermann et al., Nature 406:267-273, 2000
	C120	Steplewski et al., PNAS 85:4852-4856, 1988
	C121	Strohmeier et al., J Leukocyte Biol 58:415-422, 1995
	C122	Sylvestre and Ravetch, Immunity 5:387-390, 1996
	C123	Sylvestre and Ravetch, Sciece 265:1095-1098, 1994
	C124	Takai et al., Cell 76:519-529, 1994
	C125	Takai et al., Nature 379:346-349, 1996
****	C126	Takai, Nature Reviews 2:580-592, 2002
	C127	Tamm et al., J Biol Chem 271:3659-3666, 1996
	C128	Tao et al., J Exp Med 173:1025-1028, 1991
	C129	Tao et al., J Exp Med 178:661-667, 1993
	C130	Van Sorge et al., Tissue Antigens 61:189-202, 2003
	C131	VanAntwerp and Wittrup, Biotechnol Prog 16:31-37, 2000
*	C132	Vidarte, J Biol Chem 276:38217-38233, 2001
	C133	Ward and Ghetie, Therapeutic Immunology 2:77-94, 1995
	C134	Weng and Levy J Clin Oncol 21:3940-3947, 2003
	C135	Wing et al., J Clin Invest 98 :2819-2826, 1996
	C136	Wingren et al., Scand J Immunol 44:430-436, 1996
	C137	Wittrup, Nat Biotechnol 18:1039-1040, 2000
	C138	Witttrup, Curr, Opin. Biotechnol. 12:395-399, 2001
	C139	Woof et al., Mol Immunol 23:319-330, 1986
	C140	Wu et al., J Clin Invst 100:1059-1070, 1997
	C141	Xu et al., J Biol Chem 269 :3469-3474, 1994
	C142	Yeung and Wittrup, Biotechnol Prog 18:212-220, 2002

EXAMINER	DATE CONSIDERED

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



LIST OF REFERENCES CITED BY APPLICANT

(Use several sheets if necessary)

ATTY. DOCKET NO. 11183-004-999	APPLICATION NO. 10/754,922
APPLICANT Stavenhagen et al.	
filing date January 9, 2004	art unit 1643

. [OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)	
	C143	Zeidler et al., British J Cancer 83:261-266, 2000	
۱ ٔ	C144	Zuckier et al., Cancer Res 58:3905-3908, 1998	

EXAMINER

DATE CONSIDERED